DEC 2 1 2012

510(k) Summary
Z-Systems AG
Z-Look3 Evo SLM
K120793

October 22, 2012

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Z-Systems AG Bittertenstrasse 15 CH-4702 Oensingen, Switzerland Telephone: +41 62 388 6969 Fax: +41 62 388 6970
Official Contact:	Rubino Di Girolamo
Representative/Consultant:	Linda K. Schulz BSDH, RDH Kevin A. Thomas PhD PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: lschulz@paxmed.com kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Z-Look3 Evo SLM
Classification Name:	Implant, endosseous, root-form
Common Name:	Dental implant
Classification Regulations:	21 CFR 872.3640
Product Code	DZE
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

K120793

INTENDED USE

Z-Look3 Evo SLM implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. The Z-Look3 Evo SLM implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them.

DEVICE DESCRIPTION

Z-Look3 Evo SLM is a one-piece, root-form, threaded implant made from yttria-stabilized zirconia (Y-TZP). The Z-Look3 Evo SLM surface is grit blasted with medical grade Al_2O_3 and laser modified. Implants are available in three diameters (3.6, 4.0 and 5.0 mm) and four lengths (8, 10, 11.5 and13 mm). Z-Look3 Evo SLM implants are designed for single or multiple tooth restorations. Z-Look3 Evo SLM implants are a modification to Z-Look3 implants. The laser modified surface has been added to increase surface roughness and, therefore, the surface area available for contact with bone.

EQUIVALENCE TO MARKETED DEVICE

Z-Look3 Evo SLM is substantially equivalent in indications and design principles to the following predicate devices:

Z-Systems AG, Z-Look3 Dental Implant System, cleared under K062542;

Nobel Biocare, Zirconia Implant, cleared under K061971; and

Oral Iceberg S.L., CeraRoot Implant System, cleared under K093595;

Contour Healer, LLC. Contour Healer Temporary Abutment Cleared under K112099;

Zimmer Dental Inc., Plastic Temporary Abutment, cleared under K092377.

The subject device and the predicate devices have the same intended use and use, have similar technological characteristics and are made of the same materials. They encompass the same range of physical dimensions, including diameter and length of the implants. The subject and predicate devices are packaged in similar materials and sterilized using similar methods. Any differences in the technological characteristics between the subject device and the predicate devices do not raise new issues of safety or efficacy. The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

Overall, Z-Look3 Evo SLM has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 21, 2012

Z-Systems AG
C/O Ms. Linda Schulz, BSDH, RDH
Senior Regulatory Affairs Specialist
PaxMed International, Limited Liability Company
12264 El Camino Real, Suite 400
SAN DIEGO CA 92130

Re: K120793
Trade/Device Name: Z-Look3 Evo SLM
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 12, 2012
Received: December 13, 2012

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K120793

Device Name: Z-Look3 Evo SLM

Indications for Use:

Z-Look3 Evo SLM implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. The Z-Look3 Evo SLM implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2012.12.19 14:13:20 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120793